DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

September 28, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 106716

Al A. Taylor, CEO
Milan General Hospital
4039 South Highland
Milan, TN 38358

Warning Letter No. 01-NSV-40

Dear Mr. Taylor:

Your facility was inspected on September 6, 2001 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The system to communicate results is not adequate for site Milan General Hospital because:
- There is no system in place to provide timely lay summaries.
- There is no system in place to communicate serious or presumptive cases as soon as possible.

Level 2 (Repeat Findings)

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, [redacted], Room Mammo.

The phantom QC is not adequate for unit 1, [redacted], Room Mammo
- The operating level for background density was < 1.20.

Your facility responded to these and other noncompliances from your July 19, 2000 inspection in a letter to this office dated August 22, 2000. In your facility's response, corrective actions appeared to have been made to the above-noted deficiencies. However, the most recent inspection of September 6, 2001 reveals continuing deficiencies as demonstrated by the above-noted repeat findings.

Level 2

The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required at site Milan General Hospital.

Your facility failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of having 40 contact hours training specific to mammography.

Medical audit and outcome analysis was not done for the facility as a whole at site Milan General Hospital.

Medical audit and outcome analysis was not done separately for each individual at site Milan General Hospital.

Medical audit and outcome analysis was not performed annually at site Milan General Hospital.

There is no designated audit (reviewing) interpreting physician for site Milan General Hospital.

Not all positive mammograms were entered in the tracking system for site Milan General Hospital.

Level 3 (Repeat Finding)

The darkroom fog QC is not adequate for darkroom 1 at site Milan General Hospital because:
- The background density was < 1.20.

A response was not required for this item after your July 19, 2000 inspection because it was a Level 3 finding. A repeat Level 3 requires that your facility respond to the findings of this inspection.

Additionally, although not listed as a noncompliance by the software printing this report, your facility did not seek the services of a qualified medical physicist following major changes to your processor and obtaining new cassettes, screens and film. This is considered to be the equivalent of a Level 2 finding. You should also respond to this finding.

These specific deficiencies appeared on the Post Inspection Report given to your facility, along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies identified above and to promptly initiate permanent corrective action.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Carl E. Draper
Director, New Orleans District

CED:KRS:man

cc: Darlene Nalepa-Whitmill
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